**Remarks**

Claims 1 – 11, which were pending in this application, have been canceled and replaced by new claims 12-25. Therefore, claims 12-25 are now pending in this application.

In the Office Action dated November 2, 2005, the Examiner rejected the claims under 35 U.S.C. §112, first paragraph; under §112, second paragraph; under §101; and under the judicially created doctrine of double patenting. Specifically, the Examiner rejected claim 1 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. The Examiner rejected claims 1 -11 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner rejected claims 1 -11 under 35 U.S.C. §101, as allegedly constituting a claim which is not a proper process claim under §101. Additionally, the Examiner rejected claims 1 -11 under the judicially created doctrine of double patenting, in view of claims 1 – 11 of co-pending Application No. 10/727,658, and further in view of Applicants' admitted prior art of record.

This response addresses all of the Examiner's rejections. In light of the rewritten claim set and the discussion herein, Applicants respectfully request reconsideration of this application. Applicants believe that this application is now in condition for allowance.

*New claims*

New claims 12-23 constitute a reformulation of original claims 1–11, except that claim 8 has been rewritten as two claims, claims 19 and 20, in response to the Examiner's rejection of claim 8, as described below. Therefore, support for new claims 12-23 is found in original claims 1–11.

Support for new claims 24 and 25, which are directed to dosing sequences for producing the combination therapy, is found in the specification at paragraph [0019].

*Rejections under 35 U.S.C. §112, second paragraph, and 35 U.S.C. §101*

In order to discuss the rewritten claims, Applicants take the liberty of addressing the Examiner's second and third rejections at the outset of this response. As noted above, the Examiner rejected claims 1-11 under 35 U.S.C. §112, second paragraph, as allegedly indefinite because the claims do not set forth any steps involved in the method or process. Additionally, the Examiner rejected claims 1-11 under 35 U.S.C. §101, as allegedly constituting claims which are not proper process claims under §101, because they allegedly recite a use without any positive steps delimiting how this use is actually practiced. Additionally, the Examiner asserted that the phrase "e.g." in claim 8 rendered that claim indefinite, and the Examiner further alleged that the presence in one claim of two ranges, namely a broader range and a narrower range within that broader range, is also considered indefinite.

In response, Applicants have rewritten the claims in method-of-treatment format, where "...comprising administering to a patient in need thereof...a combination..." constitutes the positive step for practicing the claimed method. Since the absence of such step was the basis for the Examiner's rejection of claims 1-11 under 35 U.S.C. §101, Applicants respectfully assert that the rejection under 35 U.S.C. §101 has been overcome.

In response to the Examiner's rejection of claim 8, under 35 U.S.C. § 112, second paragraph, Applicants have redrafted original claim 8 as claims 19 and 20, separating the broad and narrow ranges to which the Examiner referred. Since the Examiner's rejection under 35 U.S.C. § 112, second paragraph, was based on 1) the absence of active, positive steps involved in the practice of the claimed method; and 2) the presence of the phrase "e.g.;" and 3) the presence in claim 8 of a broad range and a narrow range within the broad range, and since all three conditions have been removed from these claims by redrafting, Applicants respectfully assert that the rejection under 35 U.S.C. § 112, second paragraph, has also been overcome.

*Rejection under 35 U.S.C. §112, first paragraph*

With regard to the rejection under 35 U.S.C. §112, first paragraph, Applicants respectfully submit that the Examiner has failed to satisfy his initial burden of setting forth express findings of fact which support a conclusion of lack of written description, as required by MPEP §2163.04. Under MPEP §2163.04, without such a showing of a reasonable basis to challenge the adequacy of the written description, the description as filed must be presumed to be adequate to support the claims.

Noting principles enunciated in MPEP §2163 II A that "[t]he examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims," Applicants respectfully submit that the Examiner's rejection under §112, first paragraph, lacks any such evidence or reasoning. Applicants note that the Examiner has paraphrased the claim and then, without explanation, has selected for citation only two out of the specification's ten references which disclose reduction in muscle tone by sodium channel-inhibiting and influencing substances.

Specifically, the Examiner has appeared to overlook the following: Naesler *et al. Anesth Analg* 2001: 92, 1192-8, which discusses reduction of muscle tone by the sodium channel inhibitor propofol; Kennel *et al. J. Neurol Sci* 2000; 180: 55-61, which discusses the anti-excitotoxic effects of the sodium channel inhibitor riluzole and the effect of that compound in retarding the progress of functional parameters associated with muscle strength; De Luca *et al. J. Pharmacol Exp Ther* 1997; 282: 93-100, which discloses the antimyotonic effect of the sodium channel blocker metilexin; Duranti *et al. Eur J Med Chem* 2000; 35:147-56, which describes the relief of hyperexcitability of skeletal muscle by metilexin; Rosenfeld *et al. Ann. Neurol* 1997; 42:811-14, which describes the dramatic resolution of non-dystrophic myotonia by the sodium channel inhibitor flecainide, as well as the review article by Obrenovitch *Int Rev Neurobiol* 1997: 40: 109-35, all of which are cited in the specification at Paragraph [0004]. It will be noted that in addition to disclosing additional sodium channel inhibitors which can be used to practice the present invention, the forgoing references also disclose a broad variety of pain types which

can be treated using the claimed combination. Additionally, the Examiner has also not cited any of the several references which discuss lidocaine in comparison with tolperisone (e.g., Strathman 2002, www.ifap-index.de/bda/hausarzt/19-2002/6483.prf and Bastigkeit MMW-Forschr Med 2000; 142:50-51), found at Paragraph [0005].

Instead of a statement of evidence and reasoning, the Examiner immediately states -- without support --his conclusion: that claims which are directed to the genus comprising "sodium channel inhibiting or –influencing substances" or to the genus comprising "pains which are accompanied by an increase in muscle tone"

> ...necessitate[e] an exhaustive search for embodiments suitable to practice the claimed invention. None of these meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. [Office Action at page 2-3]

In response, noting first that, in contrast to the Examiner's "exhaustive search," one need search no further than Paragraphs [0004], [0005], and [0015] for additional embodiments, Applicants respectfully direct the Examiner's attention to MPEP §2163 IA, wherein it is stated: "there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." Under MPEP §2163.04, without a showing of a reasonable basis to challenge the adequacy of the written description, the description as filed must be presumed to be adequate. Applicants respectfully submit that because the Examiner has not made a *prima facie* case for lack of written description, the rejection under 35 USC §112, first paragraph, is improper.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

*Double Patenting Rejection*

The Examiner has rejected claims 1-11 under the judicially-created doctrine of double patenting over claims 1-11 over commonly owned copending Application Ser. No.10/727658, in

view of Applicants' prior art of record, particularly Kornhuber *et al.*, *J. Neural. Transm.* 1999; 106:857-67, alleging that the claims of the two applications are not patentably distinct. In response, without acknowledging the propriety of the rejection, and solely in an effort to expedite prosecution of this application, Applicants have provided with this response a terminal disclaimer. Therefore, the nonstatutory double patenting rejection is obviated.

*Conclusion*

In view of the foregoing amendments and remarks, Applicants respectfully submit that this application is now in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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Heidi Reese

Heidi Reese
Reg. No. 57,841
BROWN RAYSMAN MILLSTEIN FELDER
& STEINER LLP
900 Third Avenue
New York, New York 10022
(212) 895-2000